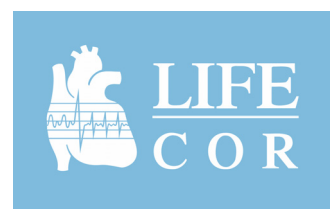
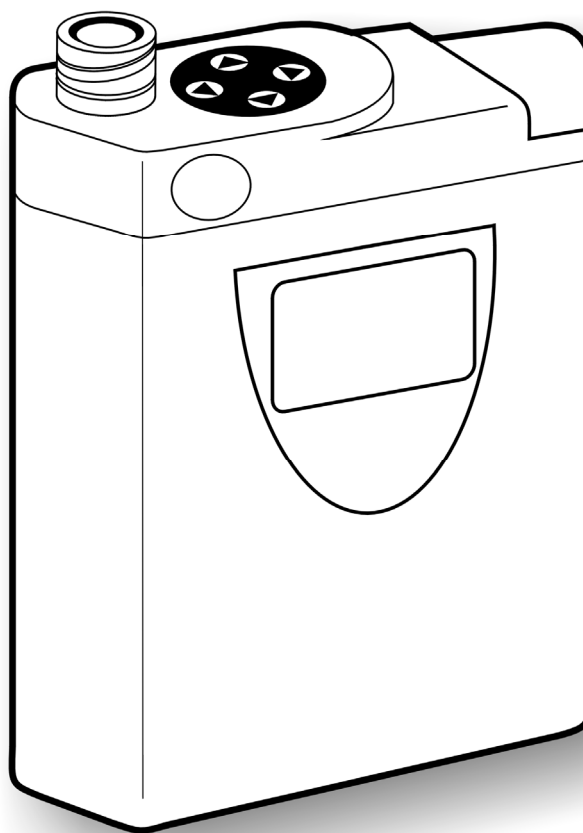




**LifeVest System
Model WCD 3100**

Operator's Manual



PN 20B0040 Rev FI

Restricted sale

Federal (USA) law restricts this device to sale by or on the order of a physician.

Effectivity

This manual describes the LifeVest® WCD™ 3100 wearable defibrillator system with software version 5.1 and up.

Disclaimer

Information, operation, specifications, and product appearance may change without notice. Names and data used in examples are fictitious.

Trademarks

Lifecor, WCD, and LifeVest are trademarks or registered trademarks of ZOLL Lifecor Corporation in the United States of America. All other product names mentioned herein are the trademarks of their respective owners.

Copyright notice

Copyright 2006 Zoll Lifecor Corporation.

Patents

US patents: 6,681,003; 6,280,461; 6,253,099; 6,169,387; 6,097,982; 6,065,154; 5,944,669; 5,929,601; 5,741,306; 5,078,134; 4,928,690; others pending.

Software nonexclusive license

The LifeVest device includes certain software ("Software"). ZOLL Lifecor grants you a nonexclusive license to use the Software solely for diagnostic and treatment purposes as part of use of the LifeVest device. You are prohibited from: (i) reproducing the Software; (ii) removing or destroying any proprietary markings, copyright notices or other legends which are part of the Software; (iii) modifying or reverse engineering the Software; or (iv) removing the Software from the LifeVest device. Title to the Software will remain at all times with ZOLL Lifecor. You must keep the Software confidential.

Contact information

ZOLL Lifecor Corporation
121 Freeport Road
Pittsburgh, PA 15238-3495
USA

Phone 412-826-2146
Toll free (USA) 1-800-LIFECOR (1-800-543-3267)
Fax 412-826-9485
Web www.lifecor.com

Contents

1: Introduction	1-1
About this manual	1-1
What's in this manual	1-1
About the LifeVest system	1-2
Safety information	1-5
2: Patient fitting	2-1
Before you start	2-1
Components of the LifeVest belt assembly	2-1
How to measure the patient	2-2
How to assemble the electrode belt to the garment	2-3
How to put the garment on the patient and finalize assembly	2-4
3: Patient training	3-1
Main points to teach the patient	3-1
Summary of operating modes	3-3
Demonstrating the alarms	3-4
4: Monitor setup for a new patient	4-1
About this section	4-1
Menu structure	4-1
How to put the monitor in setup mode	4-2
How to set up a new patient	4-4
How to baseline a patient	4-5
How to manually re-baseline a patient	4-7
5: Data management	5-1
About LifeVest Network	5-1
How to view patient data on LifeVest Network	5-2
6: Clinical information	6-1
Indications	6-1
Contraindications	6-1
Pacemaker interactions	6-1
Recommendations for patients with pacemakers	6-2
Recommendation for double counting of a normal rhythm	6-2
Clinical studies	6-3
Appendix A: Quick charts	A-1
Appendix B: Part Numbers	B-1
Appendix C: Symbols	C-1
Index	

This page intentionally left blank.

1: Introduction

About this manual

This manual:

- is for operators of the LifeVest wearable defibrillator.
- gives you instructions on how to fit patients, as well as instruct patients in the use and care of the device.
- supplements the patient manual, which gives patient instructions on the use and care of the LifeVest device.

What's in this manual

Here's how to use this manual:

- The next few pages contain details about the LifeVest system, plus safety information.
- **Patient fitting** explains how to fit a patient and assemble the components of the LifeVest belt.
- **Patient training** gives guidelines for instructing the patient about the LifeVest system and how to respond to alarms.
- **Monitor setup for a new patient** covers the basic procedures and menus for setting up the monitor before use by a new patient. (If you need to change other settings, see the programming section of the Service Manual.)
- **Data management** tells how to view patient data on the LifeVest Network using a computer with Internet access.
- **Clinical information** contains indications, contraindications, a summary of the clinical studies, and other clinical details.
- Appendixes include **Quick charts**, **Part numbers**, and **Symbols**. The quick charts are particularly helpful as reminders of how to do things.
- Use the **Index** at the back of the manual to find what you're looking for quickly.

About the LifeVest system

The LifeVest is a cardioverter defibrillator worn by a patient at risk for sudden cardiac arrest (SCA). It monitors the patient's heart continuously and, if the patient goes into a life-threatening arrhythmia, can deliver a shock treatment to restore the patient's heart to normal rhythm.

Two main components

The LifeVest system consists of two main components: (1) an electrode belt and garment that surrounds the patient's chest, and (2) a monitor that the patient wears around the waist or from a shoulder strap.

Washable garments are available in sizes to suit most patients. The LifeVest device's electrodes are dry and non-adhesive to provide patient comfort.

The monitor weighs about 1.8 pounds, making it the lightest external defibrillator available. The device contains pushbuttons and indicators for the user, as well as a speaker for sounding alarms and voice prompts.

Treatment cycle less than a minute

When the device detects a treatable arrhythmia, an alarm sequence begins, giving a conscious patient time to stop the treatment. This keeps inappropriate arrhythmia detections from becoming inappropriate shocks, a key difference between the wearable defibrillator and an implanted defibrillator.

If the patient holds the two "response" buttons at any time during the treatment sequence, the alarms stop and no shocks will be delivered.

If the patient does not respond or releases the response buttons, the device continues to give alarms and spoken warnings to bystanders that a treatment shock is about to be delivered.

Gel within the electrodes is released just prior to delivering the treatment shock in order to deliver the shock most efficiently.

The entire event, from arrhythmia detection to delivery of the shock treatment, typically takes less than one minute.

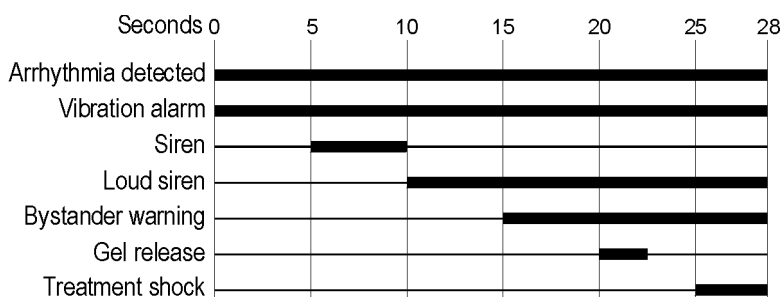
If the arrhythmia continues after the first shock, up to 5 shocks may be given.

Treatment sequence

After identifying VF, there is a response time of 25 seconds (programmable up to 55 seconds) to allow the patient time to respond to the alarms, as shown below. The lower threshold for VF identification can be set from 120 to 250 beats per minute (bpm), with a default of 200 bpm.

If the system identifies VT, there is a response time of 60 seconds (programmable up to 180 seconds). The lower threshold for VT identification can be set from 120 to the VF threshold, with a default setting of 150 bpm.

Typical treatment sequence during ventricular fibrillation



The LifeVest device can deliver up to 5 defibrillating pulses during an arrhythmic episode. The energy of the pulses can be programmed individually to between 75 and 150 joules ($\pm 5\%$), with a default setting of 150 joules.

ECG recording of events

The patient's electrocardiogram (ECG) is recorded for all detected arrhythmias, including before and after treatment. The patient can also manually record an ECG at any time by pressing the response buttons on the device.

Patients transmit information from their devices by telephone to the LifeVest Network. Physicians can then access their patient's information from virtually any computer with an Internet connection. LifeVest Network allows physicians to view ECG recordings, patient use, ECC interference, and other device-related information.

Biphasic waveform delivers efficient energy

The LifeVest device delivers its defibrillating energy in a biphasic truncated exponential waveform, whereby the signal goes positive, then negative very quickly. This type of waveform has been shown to be effective defibrillating at lower energy levels.

The amplitude and width of the phases of the energy waveform are automatically adjusted to deliver a precise energy amount regardless of the patient's body impedance.

Reliable detection algorithm

The LifeVest has proved to be effective at detecting ventricular tachycardia (VT) and ventricular fibrillation (VF). The detection algorithm was 100% sensitive for VF and 95% sensitive for VT in bench testing. The algorithm uses the patient's baseline vectorcardiogram as a template for detecting changes in cardiac signal morphology in addition to standard rate determination of arrhythmias.

Safety information

This information helps you safely operate the LifeVest system. Read and understand these warnings, cautions, and symbols before using the device.

Terms used

WARNING: Alerts of possible injury or death caused by misuse of the device. This includes device failure that could lead to the patient not being protected by the device.

CAUTION: Alerts of a possible problem with the device. Such problems include damage to the device or other property, or minor injury.

Rescue defibrillation

- If the patient should require conventional defibrillation, a warning label on the garment informs medical personnel to unfasten and lay open the garment, thus removing the front therapy pad from the patient's chest. If medical personnel fail to do so, the LifeVest device may interfere with the defibrillation, and the conventional defibrillator may damage the device.

Shock hazard

- Do not attempt to open the monitor, battery, battery charger, or modem. This may expose you to high voltage and damage the system.

To help ensure proper operation

- Use only the cables, batteries, and accessories specified in this manual. If you use any other items, the system may not operate correctly.
- Operate the system within the range of 0°C to 50°C (32°F to 122°F), up to 95% relative humidity (non-condensing), and up to 10,000 feet in altitude.

This page intentionally left blank.

2: Patient fitting

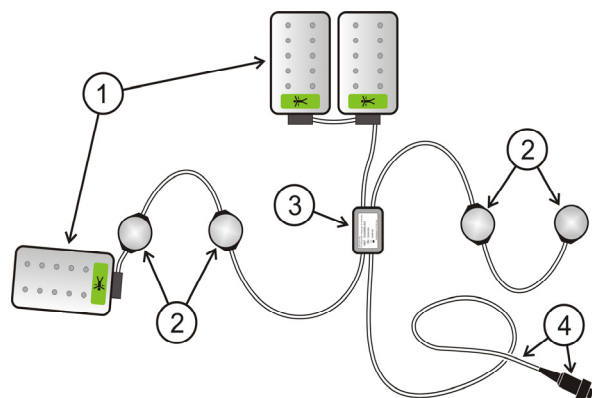
This section explains how to fit a patient and assemble the components of the LifeVest belt.

Before you start

- Gather the electrode belt and garment.
- Read through these procedures completely.
- Familiarize yourself with the components and what they're called.
- Have a clean, flat area to lay out and assemble the components, such as a table or counter. You might want to put a towel or cloth on the table to protect the components as you assemble them.

Components of the LifeVest belt assembly

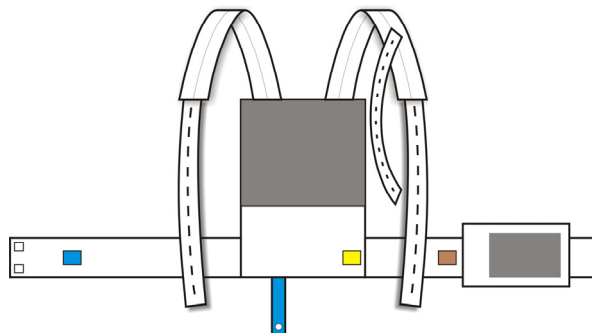
Electrode Belt



The electrode belt comes in one size and fits any patient. The parts of the electrode belt are as follows:

- 1 Therapy pads
- 2 ECG electrodes
- 3 Vibration box
- 4 Cable and connector

Garment

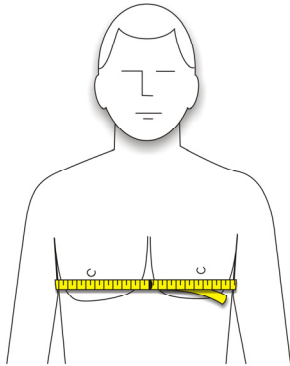


The garment comes in a variety of sizes to suit the patient.

In this chapter, you will measure the patient to determine what size garment to use.

How to measure the patient

Measure the patient to determine what size garment to use.



- 1 Have patient stand and remove all upper body clothing, including undergarments.
- 2 Place a measuring tape around the patient's chest, centered at the xiphoid. Measure to the closest inch or centimeter.
- 3 Find the patient's measurement in the chart below and get the size garment indicated.

Chest measurement		Garment 10A0964-A0X
inches	centimeters	
26-27	66-70	A01
28-30	71-78	A02
31-33	79-85	A03
34-36	86-93	A04
37-40	94-103	A05
41-45	104-116	A06
46-50	117-128	A07
51-56	129-142	A08

Note: The sizes in this chart are suggested sizes. You may vary from the sizes indicated in order to suit patient.

Example: Patient measures 44 inches. Read the chart to locate this measurement.

Chest measurement		Garment 10A964-A0X
inches	centimeters	
26-27	66-70	A01
28-30	71-78	A02
31-33	79-85	A03
34-36	86-93	A04
37-40	94-103	A05
41-45	104-116	A06
46-50	117-128	A07
51-56	129-142	A08



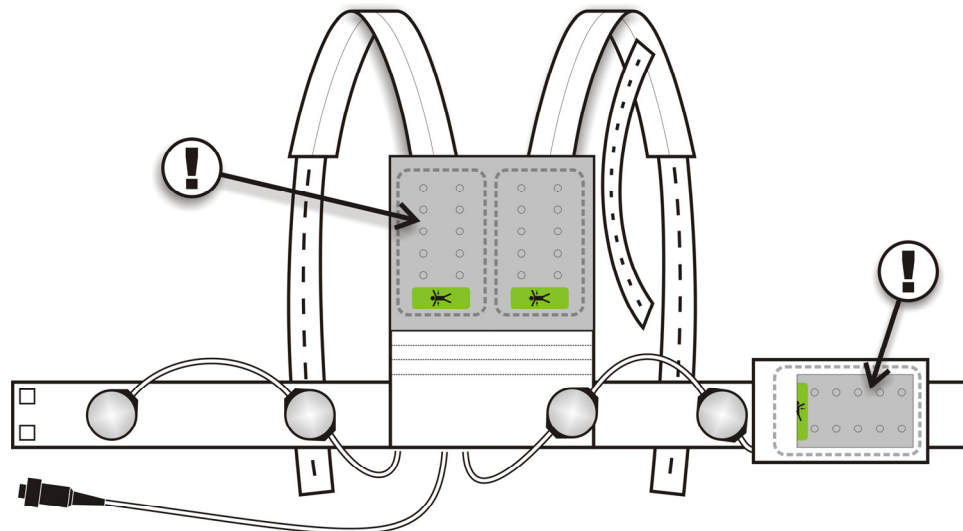
According to the chart, patient needs garment A06

How to assemble the electrode belt to the garment

Assemble the belt and garment as described in the Patient Manual, but do not fasten the straps. The fully assembled electrode belt and garment should look like the following figures.

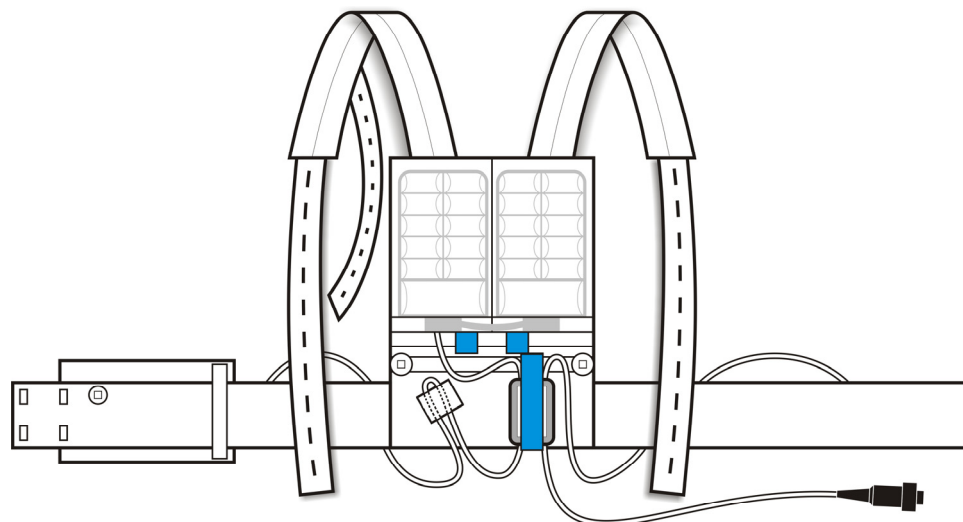
Toward patient's body

Make sure that this side faces toward the patient's body.



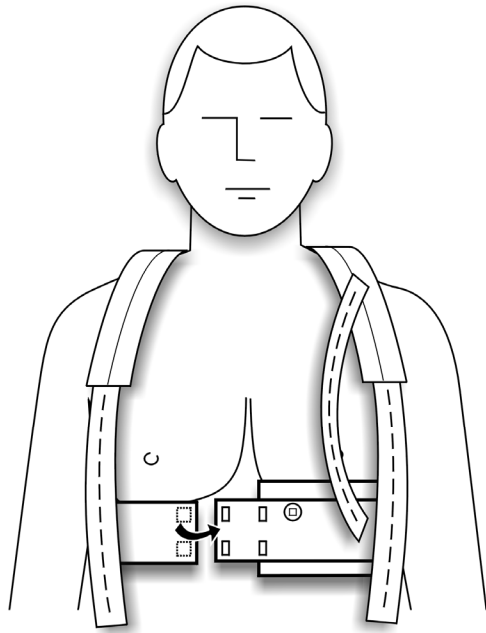
Away from patient's body

Make sure that this side faces away from patient's body.

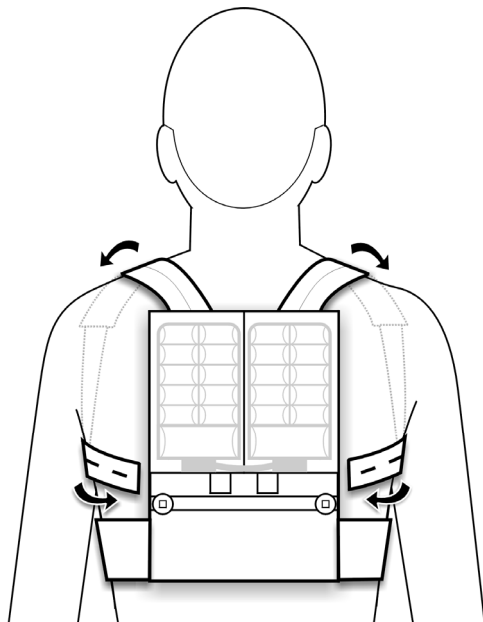


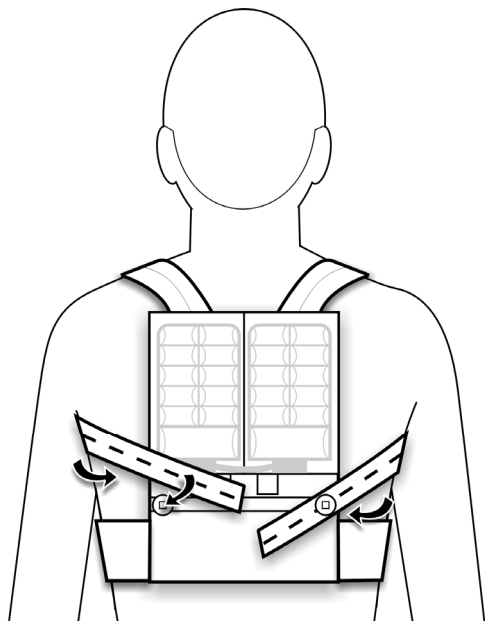
How to put the garment on the patient and finalize assembly

Place the garment and belt assembly on the patient as follows.

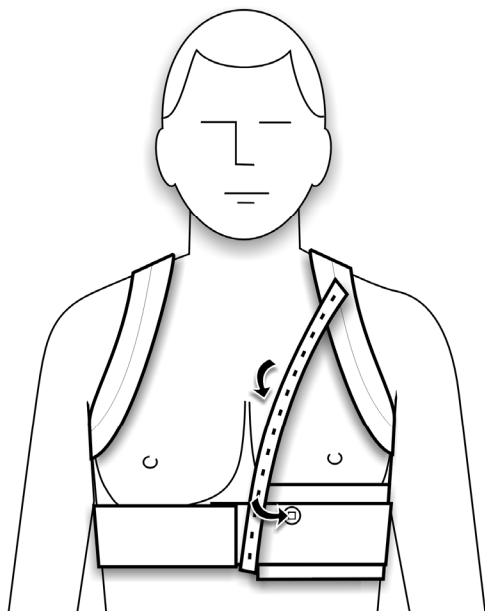


- 1 All clothing and undergarments must be removed before putting on the garment. All clothing, including underwear, must be worn over the device, not under it.
- 2 Apply unscented hand lotion or skin cream to the four ECG electrodes.
- 3 Help the patient put on the garment. Connect the ends of the garment together in the front.
 - Make sure that the garment doesn't get twisted as the patient puts it on.
 - Tell the patient that the metal mesh pockets must touch bare skin in order for a defibrillating pulse to be delivered.
 - Female patients should be encouraged to wear a bra over the garment. Make sure the metal surface of the front therapy pad presses against the patient's body rather than the underside of her left breast.
- 4 Position straps over the patient's shoulders and bring them under the patient's arms around to the patient's back.

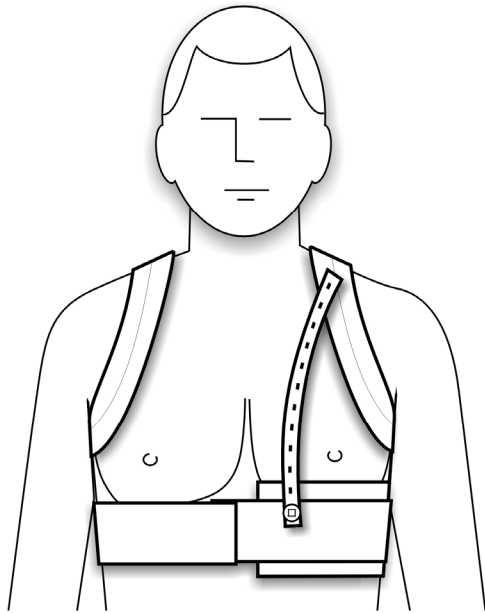




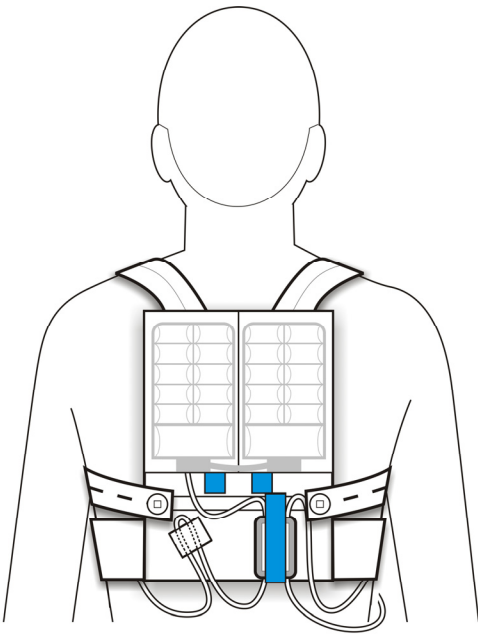
- 5 Without stretching the strap, find the hole that lines up with the button. Then stretch the strap slightly and attached the button to the next hole.
- Do not cut the strap.
 - Excess strap can be folded over and buttoned again.
 - Repeat for each of the two long straps.
 - Adjust the garment for a good fit.



- 6 Bring the remaining strap down the front of the patient's chest and button it to the front of the garment.
- Do not cut the strap.
 - Excess strap can be folded over and buttoned again.



At left is the garment and belt assembly as viewed from the patient's front.



7 Have the patient look in a mirror to make sure that:

- Garment and belt assembly is being worn correctly.
- Garment is not twisted.
- Electrodes and therapy pads are pressing against bare skin.

3: Patient training

This section gives guidelines for instructing the patient about the LifeVest system and how to respond to alarms.

We suggest that you:

- 1 Go over the main points below.
- 2 Explain the operating modes and alarms as described on page 3-3.
- 3 Demonstrate the types of alarms that can occur as described on page 3-4.

Main points to teach the patient

When you instruct the patient, stress the following points, explained below and on the following page:

- If you get a siren alarm, hold the response buttons.
- If you get a gong alarm, read the message.
- If you get shocked, call your doctor and send data.
- Review the Patient Manual so that the patient is familiar with its contents and where to find things.

If you get a siren alarm, hold the response buttons

- The response buttons will light red when you are to press them so they will be easy to find, even in the dark.
- As long as you are able to, hold the response buttons to stop a treatment. As long as you remain conscious and hold the response buttons, you are in no danger of receiving a treatment shock.
- If you lose consciousness, of course you will not be able to hold the response buttons. In this case, and if the lethal heart rhythm continues, the device will go through the treatment cycle and deliver a treatment shock.
- It is very important that only you (the patient) hold the response buttons. This is how the monitor knows whether or not you are conscious. **DO NOT** let anyone else hold the response buttons for you.

If you get a gong alarm, read the message

- Read the display and do what it says to fix the problem. Check the Patient Manual (section 5) for reminders about what to do for various messages.
- Keep in mind that the monitor gives alarms, messages, and voice prompts to guide you in what to do.

If you have an event, call your doctor and send data

- If you have any kind of cardiac event, even if you manage to stay conscious and hold the response buttons, you should contact your physician and report the incident.
- Any cardiac event is recorded by the monitor so you can send the data later.
- As soon as possible after any cardiac event, you should send data using the modem.

Review the contents of the Patient Manual

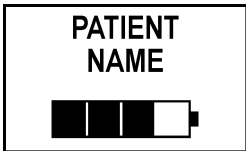



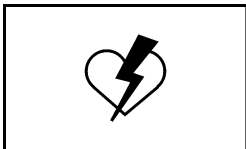

Review how to:

- change and charge the battery
- change the garment
- disassemble and reassemble the garment and electrode belt
- send data using the modem

Also be sure to review the warnings and cautions located in the Patient Manual.

Summary of operating modes

As you instruct the patient, keep in mind that the device has basically three operating modes:

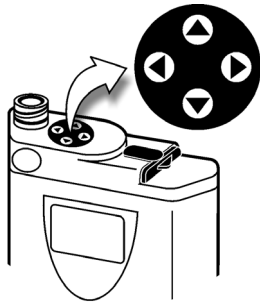
Mode	Message	What it means	What the patient needs to do
Normal monitoring – no alarms	 <p>PATIENT NAME [Battery icon]</p>	Monitor is operating normally.	Nothing.
Gong alarm	<p>Various messages can appear, for example:</p>   	Patient needs to take action.	<p>Read monitor and do what it says.</p> <p>Check Patient Manual for more information. See section 5, <i>If you get alarms</i>.</p>
Siren alarm	 <p>and</p> 	An arrhythmia is being detected.	<p>Press and hold the response buttons if conscious.</p> <p>Check Patient Manual for more information. See section 5, <i>If you get alarms</i>.</p>

Demonstrating the alarms

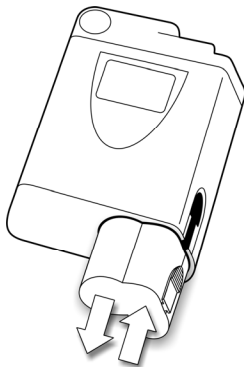
Demonstrate the alarms to help the patient learn how to respond. Follow the procedures below to:

- Place the system in training mode, then
- Simulate alarm conditions.

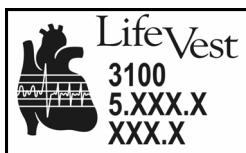
How to enter training mode



View the navigation buttons from the top of the monitor with the display facing you.

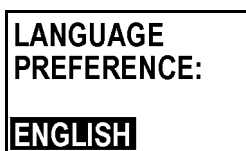


- 1 Remove and reinsert the battery.



- 2 While the opening screen is displayed, hold the response buttons and hold ◀ at the same time. Continue holding these buttons until the screen changes.

This screen may be displayed for more than 10 seconds.



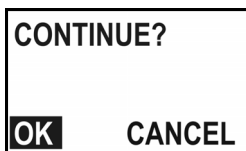
- 3 Press ▲ or ▼ to choose a language, then press ►.



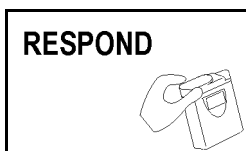
- 4 With **PATIENT** selected, press ►.



- 5 Press ▲ or ▼ to select **TRAINING**, then press ►.



- 6 Press ► to select **OK**, then press the response buttons.

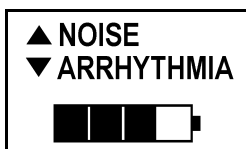
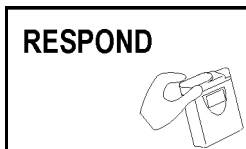


- 7 Press the response buttons again.



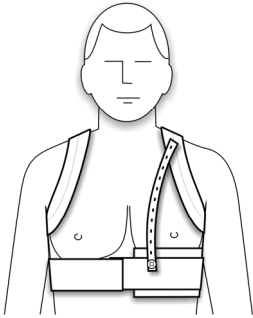
- 8 The monitor is now in training mode, with these messages alternating.

Press the response buttons to silence the gong alarm.

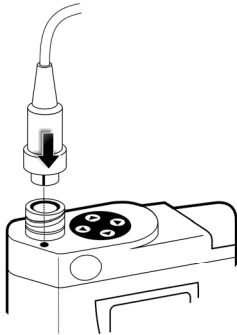


- 9 The monitor is ready to demonstrate the noise and arrhythmia alarms.

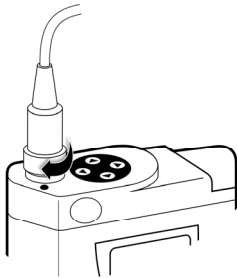
Connect patient for training mode



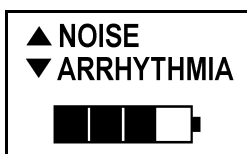
- 1 Outfit the patient with the electrode belt and garment.



- 2 Connect the electrode belt to the monitor.
- 3 Continue with the procedures on the next page.



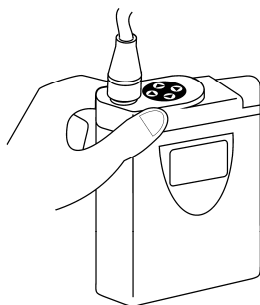
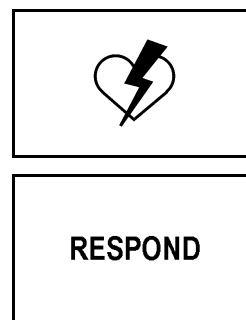
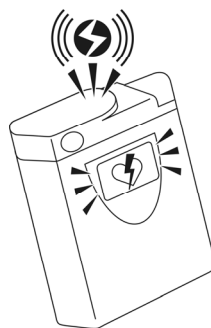
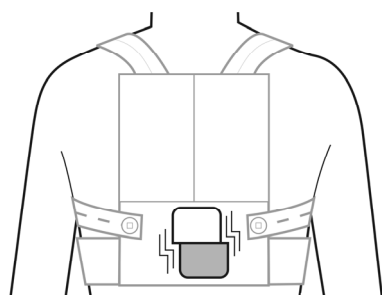
How to demonstrate the arrhythmia alarms



- 1 With this screen displayed, press ▼.

The device runs through the alarm sequence that will occur if an arrhythmia is detected:

- Vibration alarm activates and response buttons light red.
- Siren alarm sounds.
- Display shows that an arrhythmia has been detected and tells patient to press response buttons.
- Voice prompts announce to bystanders that that patient is going to be shocked.



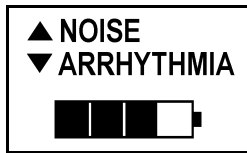
- 2 Tell the patient to press and hold the response button during the alarms.

The alarms stop as long as the patient holds the response buttons.

Tell the patient to release the response buttons to show that the alarm sequence resumes.

- 3 To stop the arrhythmia demonstration, press ▼.

How to demonstrate a noise alarm



- 1 With this screen displayed, press ▲.



- 2 Tell the patient what to do when the gong alarm sounds:
 - Read the display. This particular message states that ECG signal is not clear. The ECG electrodes are not sending a good signal to the monitor.
 - Take action to correct problem. In this case, adjust the belt so that the ECG electrodes make better contact with the skin.
 - Press response buttons if display so states. This stops the gong alarm.



- 3 With a noise alarm, when you press the response buttons, the monitor checks for an improvement in the ECG signal.

For the demonstration, the ADJUST BELT message returns.



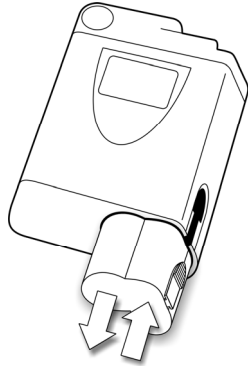
- 4 After three cycles, the monitor displays this message.

When this happens, the patient is expected to check the belt as described in the Patient Manual.

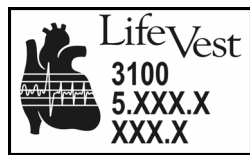
Pressing the response buttons does not make this message go away.

- 5 To stop the noise alarm demonstration, press ▲.

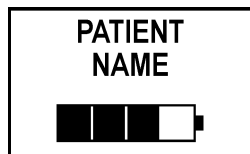
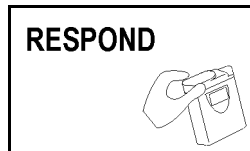
How to exit training mode



- 1 Remove and reinsert the battery.



- 2 Press the response buttons as normal.



- 3 Monitor resumes normal operation.

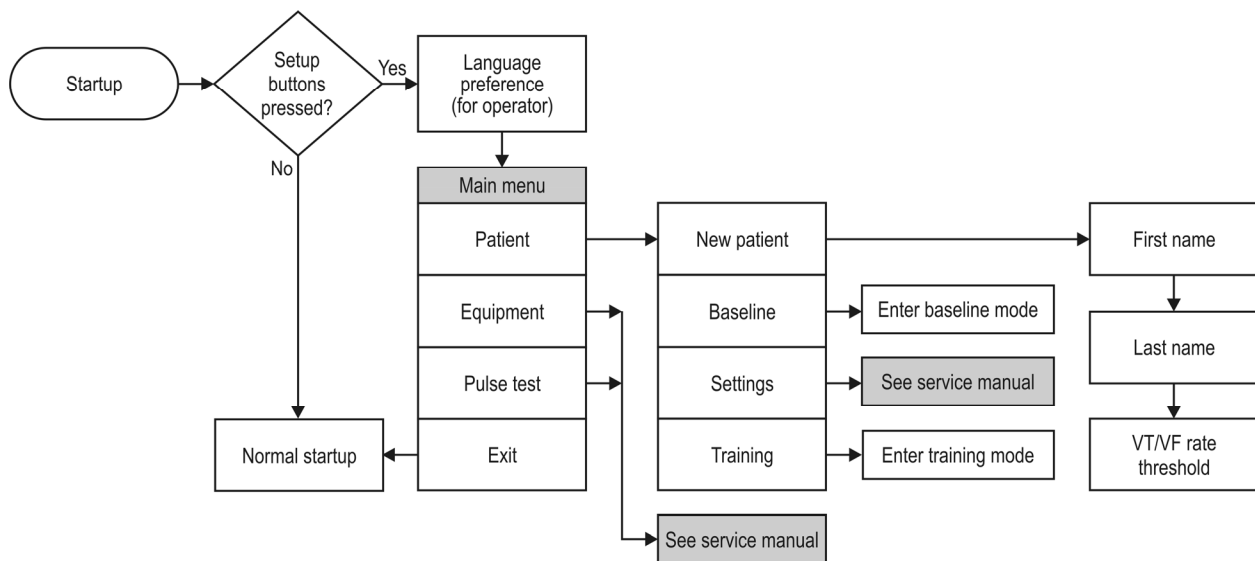
This page intentionally left blank.

4: Monitor setup for a new patient

About this section

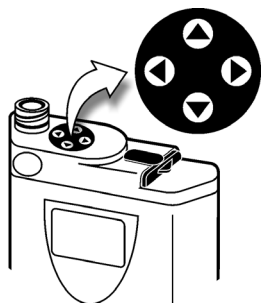
- This section covers the basic procedures and menus for setting up the monitor before use by a new patient.
- This section applies to software version 5.1 and up.
- If you need to change any other settings, see the programming section of the Service Manual.

Menu structure

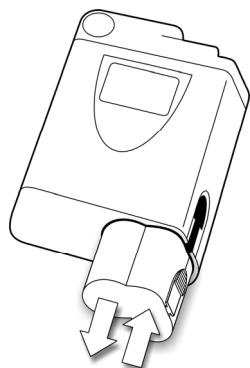


How to put the monitor in setup mode

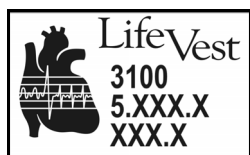
Before entering new patient information, follow this procedure to place the monitor in setup mode.



View the navigation buttons from the top of the monitor with the display facing you.

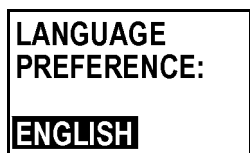
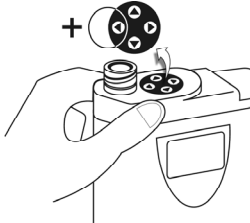


- 1 Remove and reinsert the battery.



- 2 While the opening screen is displayed, hold the response buttons and hold ◀ at the same time. Continue holding these buttons until the screen changes.

This screen may be displayed for more than 10 seconds.



- 3 Press ▲ or ▼ to choose a language, then press ►.

Note: The language you choose only affects the setup screens and will not affect the patient screens.

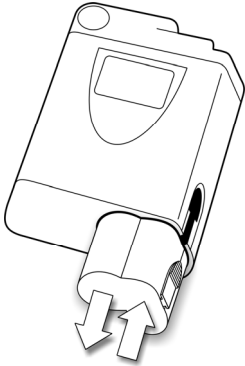


- 4 The main menu displays, showing that the monitor is in setup mode.

You may now proceed to program the monitor. See page 4-4 for details on setting up a new patient.

**PATIENT
EQUIPMENT
PULSE TEST
EXIT**

- 5 When you are finished programming the monitor, do one of the following to return to normal operation:
- Navigate back to the main menu, select **EXIT**, then press ►.
 - Wherever you are in any menu, remove and reinsert the battery.



How to set up a new patient

New patient setup consists of entering the patient's name and the rate thresholds for ventricular tachycardia and ventricular fibrillation.

PATIENT
EQUIPMENT
PULSE TEST
EXIT

- 1 With the monitor in setup mode (see page 4-2), and with **PATIENT** selected, press ►.

NEW PATIENT
BASELINE
SETTINGS
TRAINING

- 2 With **NEW PATIENT** selected, press ►.

Note that the response buttons light red to show you are in edit mode.

FIRST NAME:
A

- 3 Enter patient's first name (or ID number) as follows:
 - Press ▲ and ▼ to select characters.
 - To advance to next character, press ►. To go back, press ◀.
 - To save the name, press the response buttons.

LAST NAME:
A

- 4 Enter patient's last name. Follow same procedure as with first name.

VT/VF RATE
THRESHOLD (BPM)
VT VF
150 200

- 5 To accept the values shown for the rate thresholds without changing them, press the response buttons.

To change one or both values:

- Use ► or ◀ to select the threshold you want to change.
- Then press ▲ or ▼ to change the value.
- Repeat to change the other value.
- To save the new values, press the response buttons.

VT/VF RATE
THRESHOLD (BPM)
VT VF
150 **200**

PATIENT
NAME
CENTER NAME
OK CANCEL

- 6 Press ► or ◀ to select **OK**, then press the response buttons.

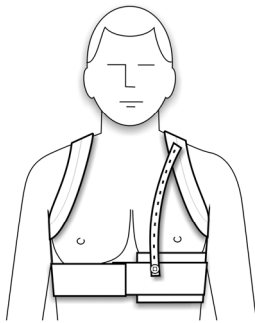
Baseline the patient as described on the next page.

How to baseline a patient

The monitor's arrhythmia detection algorithm uses the patient's baseline ECG as a template to help determine if a treatable arrhythmia exists.

When you set up a new patient, the monitor automatically goes into the baseline mode when you exit the setup mode or the next time the system powers up.

Follow this procedure to baseline the patient.



- 1 Prepare the patient, attach the garment and electrode belt, and connect the electrode cable to the monitor.

Have the patient sitting or lying down, relaxed, and not talking or moving around.

Put a fully-charged battery into the monitor.

**READY TO
RECORD**

- 2 When you see the READY TO RECORD message, press the response buttons.

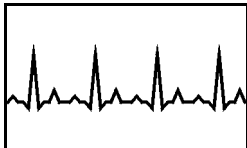
RESPOND



**RECORDING
BASELINE**

This message displays while the monitor records the baseline. The monitor also shows the patient's ECG.

Baseline recording time will vary depending on the patient, strength of the ECG signal, and the amount of noise on the ECG signal. Recording the baseline may take up to 5 minutes.



**BASELINE
COMPLETE**

RESPOND



**BASELINE
FAILED**

- 3 When you see the BASELINE COMPLETE message, press the response buttons.

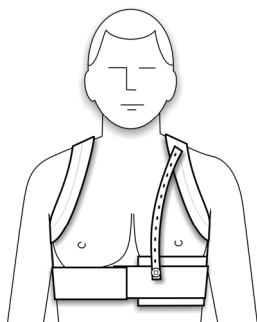
The monitor returns to normal operation.

If you get the BASELINE FAILED message, the monitor could not learn the patient's baseline. Do the following:

- Verify that the ECG electrodes are properly contacting the patient's skin. You may need to clean the skin or clip excessive hair before fitting the patient with the electrode belt and garment.
- Try to baseline the patient again. Remove the battery and repeat this procedure starting on the previous page.
- If problems continue, the patient may have a rhythm that is difficult for the monitor to learn. If so, discontinue attempting to baseline the patient and call ZOLL Lifecor.

How to manually re-baseline a patient

Use this procedure if you need to manually re-baseline a patient.



- 1 Prepare the patient, attach the garment and electrode belt, and connect the electrode cable to the monitor.

Have the patient sitting or lying down, relaxed, and not talking or moving around.

PATIENT
EQUIPMENT
PULSE TEST
EXIT

- 2 With the monitor in setup mode (see page 4-2), press ▲ or ▼ to select **PATIENT**, then press ►.

NEW PATIENT
BASELINE
SETTINGS
TRAINING

- 3 Press ▲ or ▼ to select **BASELINE**, then press ►.

CONTINUE?

OK CANCEL

- 4 Press ► or ◀ to select **OK**, then press the response buttons.

RESPOND



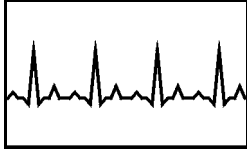
READY TO
RECORD

- 5 When you see the READY TO RECORD message, press the response buttons.

RESPOND



**RECORDING
BASELINE**



This message displays while the monitor records the baseline. The monitor also shows the patient's ECG.

Baseline recording time will vary depending on the patient, strength of the ECG signal, and the amount of noise on the ECG signal. Recording the baseline may take up to 5 minutes.

**BASELINE
COMPLETE**

- 6 When you see the BASELINE COMPLETE message, press the response buttons.

The monitor returns to normal operation.

RESPOND



**BASELINE
FAILED**

If you get the BASELINE FAILED message, the monitor could not learn the patient's baseline. Do the following:

- Verify that the ECG electrodes are properly contacting the patient's skin. You may need to clean the skin or clip excessive hair before fitting the patient with the electrode belt and garment.
- Try to baseline the patient again. Remove the battery and repeat this procedure starting on the previous page.
- If problems continue, the patient may have a rhythm that is difficult for the monitor to learn. If so, discontinue attempting to baseline the patient and call ZOLL Lifecor.

5: Data management

Have the patient follow the procedure in the Patient Manual to transfer patient data from the monitor to the LifeVest Network.

Follow the procedure in this section to view the data using a computer with Internet access.

About LifeVest Network

LifeVest Network is an Internet Web site for viewing patient data.

When patients send data from a LifeVest monitor using a modem, the data resides on LifeVest Network and forms a patient history of ECG recordings and other data.

You can view patient data from virtually any computer with Internet access. This data is available at any time so it can be viewed at your convenience.

LifeVest Network is a secure site that guards patient privacy. Only users with login names and passwords may enter the site. Only users with specific permission may view each patient's data.

What you can do with LifeVest Network

- View or change patient information from any computer with Internet access.
- View and print reports on patient ECG recordings, treatment events, compliance data, and noise data.
- Download and print forms for patient care.

Computer requirements to use LifeVest Network

Your computer will need to have Internet access and an Internet browser such as Internet Explorer or Netscape Navigator. You will also need the Adobe Acrobat Reader to view and print reports.

Your screens may look different

Due to product improvements, your screens may not look exactly like what's shown in this manual.

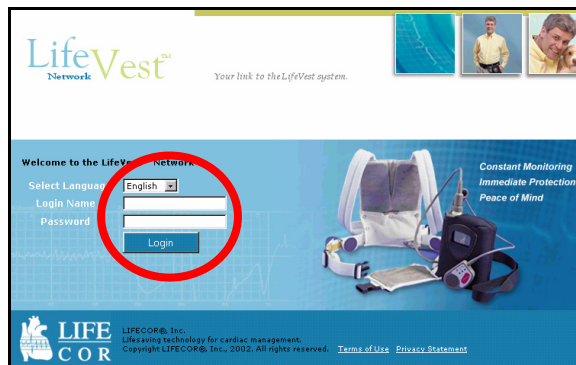
How to view patient data on LifeVest Network

This procedure requires a computer connected to the Internet.

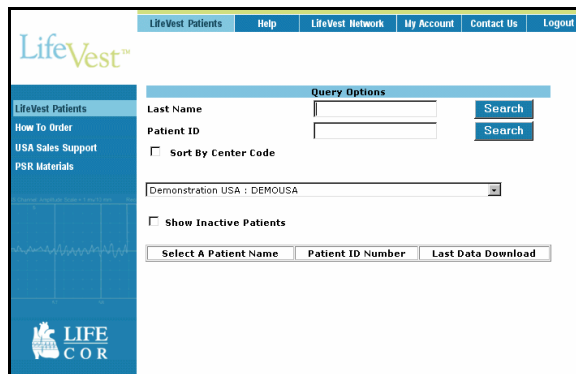
- 1 From your Internet browser, enter the LifeVest Network web site address:

<https://wcdnet.lifecor.com>

- 2 When the login screen appears, select your language preference.



- 3 Type your **Login Name** and **Password**, then click **Login**.
- 4 When the opening screen appears, select a patient name to be viewed. You can also search by the patient's last name or ID.



- 5 With a patient name displayed, click on the options along the left side of the screen to view ECG recordings, treatment events, compliance data, and noise data.

Some pages include a **Help For This Page** button along the left side. Click on the button for more detail.

- 6 Log off LifeVest Network when finished.

6: Clinical information

Indications

The LifeVest system is indicated for adult patients who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator.

Contraindications

The LifeVest system is contraindicated for use on patients with an active implantable defibrillator.

Pacemaker interactions

WARNING: Use appropriate caution when prescribing a LifeVest device to a patient who is dependent on a pacemaker. All patients who have pacemakers should be examined for proper pacemaker function after a defibrillation.

Several interactions with pacemakers are possible:

- If a patient goes into a ventricular arrhythmia and the pacemaker continues to pace, the pacemaker's pulses may be the dominant signal.¹ This may potentially cause the LifeVest device to lock on the pacemaker's signal as the cardiac rhythm and prevent the LifeVest device from detecting the arrhythmia. The risk varies according to the type of pacemaker and the programmed mode of the pacemaker.
- If the patient is baselined with the pacemaker active, an unpaced QRS complex may be interpreted by the LifeVest device as a change in the QRS morphology. As a result, if the rate goes above the arrhythmia rate threshold, the LifeVest device may then declare the unpaced rhythm a treatable arrhythmia and begin the treatment alarm sequence. As long as the patient uses the response buttons of the LifeVest device, the device will not deliver a treatment shock. However, be aware that an increased potential for an unnecessary shock does exist.
- After the shock is delivered, the pacemaker may have difficulty capturing the myocardium² or may be reset to a default mode.

¹ Glikson, et al, "Importance of Noise Reversion as a Potential Mechanism of Pacemaker-ICD Interactions," *PACE*, May 1998, 21: 1111-1121.

² Altamura, et al., "Transthoracic DC Shock May Represent a Serious Hazard in Pacemaker Dependent Patients," *PACE*, January 1995, 18 (Part II): 194-198

Other articles of interest:

Brode, et al, "ICD-Antiarrhythmic Drug and ICD-Pacemaker Interactions," *Journal of Cardiovascular Electrophysiology*, July 1997, 8:830-842.

Geiger, et al, "Interactions Between Transvenous Nonthoracotomy Cardioverter Defibrillator Systems and Permanent Transvenous Pacemakers," *PACE*, March 1997, 20 (Part I): 624-630.

Recommendations for patients with pacemakers

If the pacemaker does pace during ventricular fibrillation, there is a risk that the pacemaker stimulus artifact would be tracked by the LifeVest device as a valid heart rate during ventricular fibrillation. In order for this to occur, the pacemaker stimulus artifact must be greater than the ventricular fibrillation signal. Patients whose pacemaker stimulus artifact is greater than 0.5 mV in any ECG lead should not use the LifeVest device.

Because of the risk that the patient's unpaced ECG signal may be interpreted as a ventricular tachycardia if it exceeds the arrhythmia rate threshold, set the VT rate threshold above the maximum paced rate when a patient is baselined while being paced.

After shock delivery, check the pacemaker's programming and ability to capture.

Recommendation for double counting of a normal rhythm

Double counting of a normal rhythm is known to occur with ICDs and other rhythm analysis devices.

Patients likely to experience double counting declarations may have high T waves and/or low QRS amplitudes. If a patient does experience such false arrhythmia declarations, there are two actions which may help: increasing the arrhythmia rate threshold and/or lengthening the response time. Increasing the arrhythmia rate threshold should reduce the frequency of false arrhythmia declarations due to double counting, while lengthening the response time gives the patient additional time to respond to the alarms if a shock is not necessary.

Asystole detection

The LifeVest monitors the ECG signal and declares asystole when the amplitude of the ECG input signal falls below 100 microvolts for at least 16 seconds.

When the device declares asystole, it generates the following voice messages to notify bystanders: "Device disabled. Call ambulance."

To silence the alarms and restore the device to normal operation, remove and reinsert the battery.

Clinical studies

Initial FDA-approved study¹

Conducted between 1990 and 2001, the objective of the FDA-approved trial was to demonstrate safety (low false shock rate) and efficacy (survival after sudden cardiac arrest). There were 289 high SCA risk patients who used the device an average of 3 months. Of 8 SCA events that occurred during the trial, 6 were successfully converted. There were 6 appropriate shocks during the trial. The trial design was to demonstrate superiority of the wearable defibrillator to reliance on the EMS system for SCA treatment.

Biphasic electrophysiology laboratory sub-study²

This study was conducted between March 2001 and November 2001. Twelve patients were electively induced into VT or VF, and all 12 were converted or defibrillated with the first biphasic shock (either 70 or 100 joules). A total of 23 successful biphasic shocks were delivered. There were no post-shock arrhythmias or skin burns. The average patient impedance was 68 ± 8 ohms.

WCD 3000 clinical evaluation

This study was conducted between September 2001 and April 2002. The objective was to demonstrate the safety of the LifeVest WCD 3000 device by comparing the incidence of false arrhythmia declarations (false alarms) with the WCD 3000 device to the WCD 2000 device. The study would be considered successful if the incidence of false arrhythmia declarations was less than, or equal to, the WCD 2000 device. A minimum of 10 patients and 100 weeks of cumulative device use would be required.

A prospective, non-randomized, multi-national trial involving four centers (three U.S. centers and one European center) evaluated the safety of the WCD 3000 device with patients at risk of sudden cardiac death. Two populations at SCA risk were chosen:

- The first population consisted of patients waiting for heart transplant or patients having an equivalent cardiac status, namely New York Heart Association Class III or IV heart failure and an ejection fraction below 30 percent.
- The second patient population included acute myocardial infarction (MI) patients and patients immediately following a coronary artery bypass graft procedure. Additional requirements for both the MI and bypass patients included VT/VF within the first 48 hours or a left ventricular ejection fraction of less than 30 percent. A Killip Class III or IV 72 hours following the MI and syncopal VT/VF after 48 hours post-MI also qualified patients for WCD 3000 device use.

¹ Feldman et al., "Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patient at High Risk for Sudden Death: Results of WEARIT/BIROAD," *PACE*, 2004, 27:4-9.

² Reek et al., "Clinical Efficacy of a Wearable Defibrillator in Acutely Terminating Episodes of Ventricular Fibrillation Using Biphasic Shocks", *PACE*, 2003, 26:2016-2022.

Table 4. Patient demographics

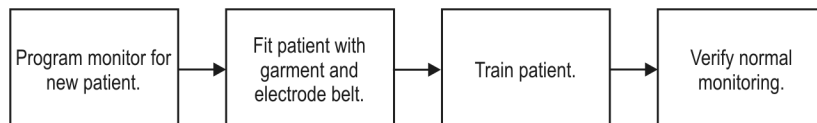
Parameter	Total Study (n=13)	WEARIT (n=7)	BIROAD (n=6)
Ejection fraction	21% \pm 7, n=11	18% \pm 6	25% \pm 5, n=4
QRS width (msecs)	105 \pm 15, n=9	106 \pm 18, n=5	104 \pm 12, n=4
Age (years)	56 \pm 11	56 \pm 13	57 \pm 9
Male	69%	71%	67%
History of smoking	83%, n=12	67%, n=6	100%
History of hypertension	83%, n=12	86%	80%, n=5
History of NSVT	89%, n=9	80%, n=5	100%, n=4
History of VT	44%, n=9	33%, n=3	50%
Beta-blocker medication	82%, n=11	67%, n=6	100%, n=5
Anti-arrhythmia medication	9%, n=11	0%, n=6	20%, n=5
Inotropic medications	0%, n=11	0%, n=6	0%, n=5

The study population consisted of 13 patients with 105 patient weeks of patient device experience. There were 214 false arrhythmia detections during that time. The rate of false detections using the WCD 3000 device was 2.0 per patient week of use as compared to 4.5 per patient week using the WCD 2000 device. There were no treatable tachyarrhythmic events during the study. There were four true arrhythmias recorded during the study, all four resolved spontaneously. There were no inappropriate defibrillations during the study.

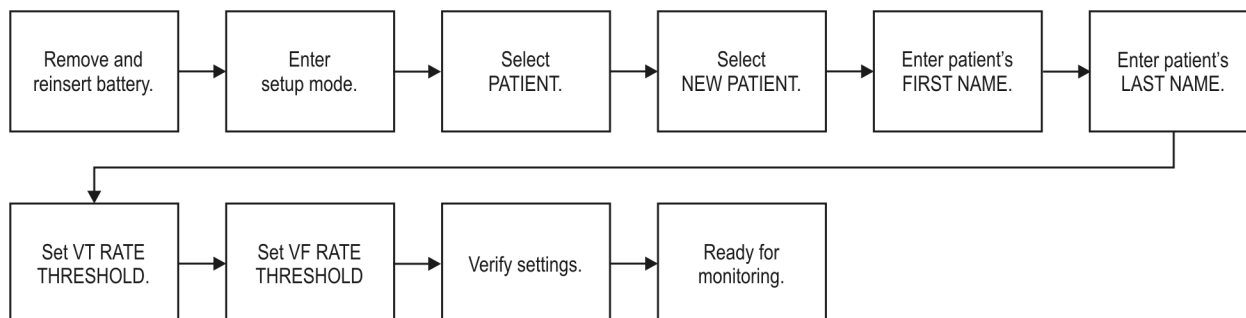
One adverse event was reported during the study. This event involved a patient who received an asystole alarm due to incompletely connecting the electrode belt to the monitor. The patient called an ambulance to take her to the hospital as the device directed. She was hospitalized as a precaution and transferred from this local hospital to the investigational site where she was examined and discharged to home. No injury resulted from this event. The patient continued to wear the device.

Appendix A: Quick charts

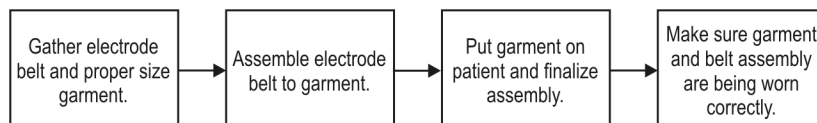
Overview of new patient setup



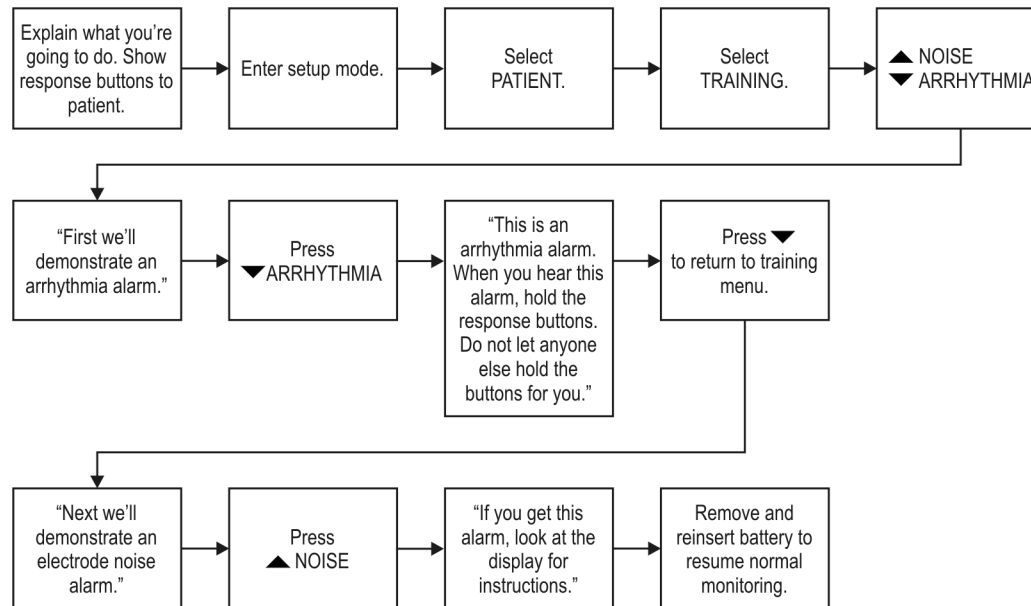
Program monitor for new patient



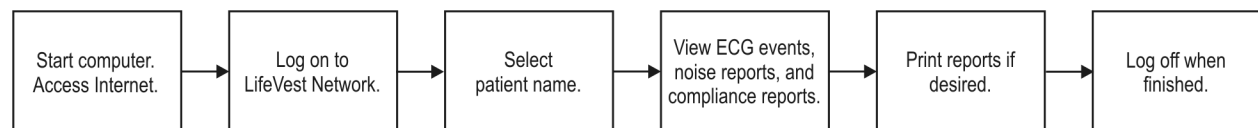
Fit patient with garment and electrode belt



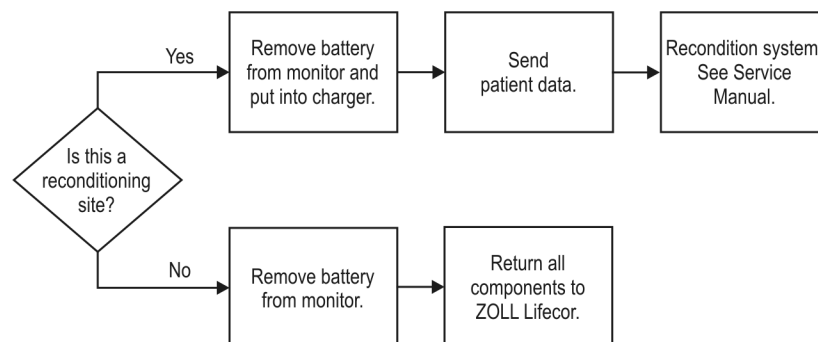
Train patient



To view patient data



When patient is finished with device
















Appendix B: Part Numbers

Description	ZOLL Lifecor Part Number
WCD 3100 Programmed Monitor	10A0967-Axx
Battery	10A0894-A01
Battery Charger with Power Supply	11B0009-A01
Modem	10A0924-A0x or 10A0903-A01
Test Plug	10A0922-A01
Holster	10B0844-A01
Electrode Belt	10A0889-A01
Garment	10A0964-A0x
Tote Bag	10B0822-A01
WCD 3100 Patient Manual	20B0039
WCD 3100 Quick Guide	20B0042
WCD 3100 Operator's Manual	20B0040
WCD 3100 Service Manual	20B0041
WCD 3100 Patient Checklist	20B0043

This page intentionally left blank.

Appendix C: Symbols

	Battery charger: Battery charged.
	Battery charger: Battery charger is charging or testing battery.
	Battery charger: Battery charger needs service.
	Battery charger: Battery needs service.
	Battery: Do not incinerate.
	Battery: Do not short circuit.
	Caution: Consult accompanying documents.
	CE marking, indicates conformance with European Medical Device Directive.
	Laundrying symbol: Normal cycle in warm water.
	Laundrying symbol: Tumble dry warm.
	Laundrying symbol: Only non-chlorine bleach, when needed.
	Laundrying symbol: No anti-static spray.
	Laundrying symbol: Iron on low temperature.



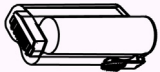
Laundrying symbol: No fabric softener.



Manufacturing date.



Monitor connector: Type BF defibrillator-proof connector.



Packaging: Battery



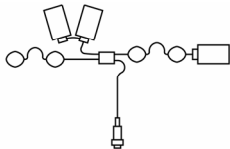
Packaging: Battery charger



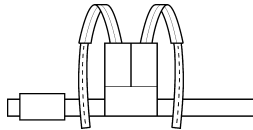
Packaging: Monitor.



Packaging: Modem.



Packaging: Electrode belt.



Packaging: Garment.



Power supply electrical information: Alternating current (AC).



Power supply electrical information: Direct current (DC).



Therapy pad label: Place this side (foil side) of the therapy pad next to your skin.

Index

A

- accessory part numbers, B-1
- address
 - ZOLL Lifecor, ii
- alarms
 - demonstrating, 3-4
- arrhythmia
 - demonstrating, 3-7
- assembly
 - electrode belt to garment, 2-3
- asystole detection, 6-2

B

- baseline, 4-5
 - failed, 4-6, 4-8
 - manual, 4-7
- basic programming, 4-4
- belt
 - components, 2-1
- BF symbol, C-2

C

- cautions, 1-5
- CE symbol, C-1
- chapters of this manual, 1-1
- chest measurement, 2-2
- clinical information, 6-1
- component part numbers, B-1
- computer
 - for LifeVest Network, 5-1
- contact ZOLL Lifecor, ii
- contents of this manual, iii
- contraindications, 6-1
- copyright, ii

D

- data management, 5-1
 - quick chart, A-2
- defibrillation
 - conventional, warning, 1-5
- demonstrating
 - alarms, 3-4
- device
 - description, 1-2
- double counting
 - recommendation, 6-2
- downloading, 5-1

E

- effectivity, ii
- exclamation point symbol, C-1

F

- fit patient
 - quick chart, A-1

G

- garment
 - sizes, 2-2
- garment and electrode belt
 - quick chart, A-1
- garment on patient, 2-4

I

- indications, 6-1
- instructing patient, 3-1
- Internet access, 5-2
- introduction, 1-1

L

- laundrying
 - symbols, C-1
- LifeVest Network, 5-1
 - computer, 5-1
 - login, 5-2
 - patient search, 5-2
- login
 - LifeVest Network, 5-2

M

- manual baseline, 4-7
- manual organization, 1-1
- manufacturing date symbol, C-2
- measure and fit patient
 - quick chart, A-1
- measure patient, 2-2
- menu
 - structure, 4-1
- monitor setup for new patient
 - quick chart, A-1

N

- new patient
 - programming, 4-4
 - programming quick chart, A-1
- new patient setup
 - quick chart, A-1
- noise
 - demonstrating, 3-8

O

- operating
 - modes, 3-3
- organization of this manual, 1-1

P

- pacemaker
 - interactions, 6-1
 - recommendations, 6-2
- packaging symbols, C-2
- part numbers, B-1
- patents, ii
- patient
 - data transfer, 5-1
 - fitting, 2-1
 - programming quick chart, A-1
 - training, 3-1
 - viewing data, 5-2
- patient finished with device
 - quick chart, A-2
- patient setup
 - quick chart, A-1
- patient training
 - quick chart, A-2
- phone
 - number, ii
- prescription note, ii
- programming, 4-1
 - basic, 4-4
 - new patient, 4-4

Q

- quick charts, A-1

R

- re-baseline patient, 4-7
- reconditioning
 - after patient is finished with device, A-2
- record baseline, 4-5
- reference guides, A-1

- rescue defibrillation, 1-5

S

- safety information, 1-5
- search patient
 - on LifeVest Network, 5-2
- sections of this manual, 1-1
- send patient data, 5-1
- setup, 4-1
 - quick charts, A-1
- setup mode, 4-2
- software license, ii
- symbols, C-1
- system
 - components, B-1

T

- teaching patient, 3-1
- therapy pads
 - label symbol, C-2
- timing
 - treatment sequence, 1-3
- trademarks, ii
- training
 - alarms, 3-4
 - arrhythmia, 3-7
 - exit, 3-9
 - mode, 3-4
 - noise, 3-8
 - patient, 3-1
- transfer patient data, 5-1
- transmitting data, 5-1
- treatment sequence, 1-3

V

- view patient data
 - quick chart, A-2
- viewing patient data, 5-2

W

- warnings, 1-5
- Web address
 - company, ii
 - LifeVest Network, 5-2

Z

- ZOLL Lifecor address, ii